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EXAMINER	
CALAMITA, HEATHER	
ART UNIT	**PAPER NUMBER**
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/870,128	IHLE ET AL.	
	Examiner	Art Unit	
	Heather G. Calamita, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-80,82,89,91 and 94-100* is/are pending in the application.

4a) Of the above claim(s) *59-61,63-79 and 94-96* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-58, 62, 80, 82, 89, 91, 97-100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. Claims 39-80, 82, 89, 91 and 94-100 are pending. Claims 39-58, 62, 80, 82, 89, 91, 97-100 are under examination. Claims 59-61, 63-79 and 94-96 are withdrawn as being directed to non-elected subject matter. All arguments have been fully considered and thoroughly reviewed, but are deemed not persuasive for the reasons that follow. Any objections and rejections not reiterated below are hereby withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 39, 40, 41, 42, 43, 44, 55, 56, 62, 89, 91 and 97 are rejected are rejected under 35 U.S.C. 103(a) as being unpatentable over Gossen et al. (USPN 5,602,300) in view of Weston et al. (USPN 5,246,851).

With regard to claim 39, Gossen teach a method for at least partially separating nucleic acid molecules in a sample into populations wherein the sample comprises a nucleic acid population tagged with a protein immobilized on a matrix, the method comprising contacting the tagged nucleic acid population with a matrix which selectively binds said protein whereby said protein interacts directly with the matrix, whereby the tagged molecules are captured by the matrix and thereby separated from untagged molecules (see col. 3 lines 1-7 and col. 4 lines 1-41, where the populations of DNA are genomic DNA and plasmid DNA, the protein is an antibody to the lacZ operator DNA, or LacI repressor protein, the

LacI repressor or the antibody to the lacZ operator directly interacts with the solid particle which is the matrix).

With regard to claim 40, Gossen teach the tag is a protein which has an affinity for a nucleic acid molecule (see col. 3 lines 1-7 and col. 4 lines 1-41, where the protein is an antibody to the lacZ operator).

With regard to claims 41,42, 89 and 91, Gossen teach the protein is a nucleic acid binding protein (see col. 4 line 22, where the LacI repressor is a DNA binding protein)

With regard to claim 43, Gossen teach the matrix is in the form of particles (see col. 4 lines 4-5).

With regard to claim 44, Gossen teach the matrix is a porous material (see col. 4 lines 4-5, where magnetic particles are porous).

With regard to claim 55, Gossen teach the nucleic acid molecules are separated into linear and circular DNA molecules (see col. 6 lines 41-49).

With regard to claim 56, Gossen teach further comprising introducing a tag to an end of the linear nucleic acid molecules, wherein said tag is a protein which is capable of being immobilized on a matrix, by direct interaction with the matrix and contacting the sample with a matrix which selectively binds proteins, whereby said tagged linear nucleic acid molecules are immobilized on the matrix (see col. 3 lines 1-7 and col. 4 lines 1-41, where the populations of DNA are genomic DNA and plasmid DNA, the protein is an antibody to the lacZ operator DNA, or LacI repressor protein).

With regard to claim 62, Gossen teach a method of separating linear from circular nucleic acid molecules in a sample said method comprising introducing a tag to an end of a linear nucleic acid molecule, wherein said tag is a protein which is capable of being immobilized on a matrix, by direct interaction with the matrix and contacting the sample with a matrix which selectively binds said protein whereby said tagged linear nucleic acid molecules are immobilized on the matrix (see col. 3 lines 1-7 and col. 4 lines 1-41 and col. 6 lines 41-49).

With regard to claim 97, Gossen teach the protein is attaches to the nucleic acid molecule (see col. 3 lines 1-7 and col. 4 lines 1-41, where the protein is an antibody to the lacZ operator DNA and the two are attached when the antibody (a protein) binds the operator).

Gossen do not teach tagging the nucleic acid population with a protein and then contacting the tagged nucleic acid with the matrix which binds the protein. Gossen teaches that the protein (the LacI repressor protein) can be bound to the matrix with a LacI antibody (see col. 4 lines 24-27). The invention of Gossen essentially functions like a sandwich assay or an ELISA. The LacI repressor binds the Lac operator and then an antibody to the LacI repressor is used to capture the LacI bound DNA. The order of binding in an ELISA or sandwich type assay is irrelevant, however Gossen et al. do not teach the order of binding is irrelevant.

Weston et al. also teach an ELISA or sandwich type assay. Weston et al. teach the order of binding is irrelevant. Weston et al. specifically teach the capturing and labeling operations may be performed in any order or simultaneously (see col. 6 lines 39-40).

One of ordinary at the time the invention was made would have been motivated to apply the method of separating nucleic acids as taught by Gossen et al. with any labeling and capture order as taught by Weston because Weston teaches that the labeling and capturing operations may be performed in *any* order. It would have been prima facie obvious to apply the method of separating nucleic acids as taught by Gossen et al. with any labeling and capture order as taught by Weston because Weston teaches that the labeling and capturing operations may be performed in *any* order. Weston establishes capturing and labeling operations are order independent and that *any* order is obvious.

3. Claims 45, 46, 80, 82, and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gossen et al. (USPN 5,602,300) and Weston et al. (USPN 5,246,851) as applied to claims 39, 43 and 44 above, and further in view of Seed (EP 0580305 A2).

The teachings and suggestions of Gossen and Weston are described previously and fully meet the

limitations of claims 39, 41, 43 and 44.

Gossen and Weston do not teach the matrix is incorporated into a separation device.

Seed teaches a matrix for separating nucleic acids is incorporated into a cartridge separation device (see example 1 lines 26-40). Additionally Seed teaches an absorbent pad is located on said porous material, a liquid impermeable sheet is located on the face of said absorbent pad remote from said porous material, and a liquid impermeable sheet having one or more holes therein is located on the face of said porous material remote from said absorbent pad, whereby the test sample is applied to one of said holes and is caused to diffuse transversely through said porous material by absorption into said absorbent pad (see example 1 lines 26-40).

One of ordinary at the time the invention was made would have been motivated to apply the method of separating nucleic acids as taught by Gossen and Weston with the cartridge housed matrix as taught by Seed in order to increase the convenience and efficiency with which DNA is separated. Seed states, "This example demonstrates the use of coated substrates to purify plasmid DNA from rapid lysates....The resulting suspension was transferred to a cartridge similar to that described in example 1, except that the cartridge also contained a cylindrical bundle of PHS-coated axially oriented polyester fibers... (see example 10 line 13-14 and 27-31)." It would have been prima facie obvious to apply the method of separating nucleic acids as taught by Gossen and Weston with the cartridge housed matrix as taught by Seed in order to increase the convenience and efficiency with which DNA is separated. A single use cartridge housing the streptavidin bound matrix would be easy to store and use as exemplified by Seed.

4. Claims 47-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gossen et al. (USPN 5,602,300) and Weston et al. (USPN 5,246,851) as applied to claim 39 above, and further in view of Davis et al. (WO 90/12115).

The teachings of Gossen and Weston are described previously and fully meet the limitations of claim 39.

Gossen and Weston do not teach PCR of the separated DNA fragments, and detection of mutations in the amplified fragments.

Davis et al. teach PCR of DNA fragments and detection of mutations in the amplified fragments (see abstract, p. 24-31).

One of ordinary at the time the invention was made would have been motivated to apply the method of separating nucleic acids as taught by Gossen and Weston with subsequent PCR and mutation detection as taught by Davis et al. in order to rapidly identify mutations in target DNA fragments. Davis et al state "By using the methods and products of this invention, it is possible to determine the genotype of an individual at any locus of interest. A single nucleotide position on a strand of DNA may be responsible for polymorphism or allelic variation. There are known disease states that are caused by such variation at a single nucleotide position. The usefulness of detecting such variation inculudes but is not limited to gene typing, karyotyping, genotyping, DNA family planning, diagnostics...(see p. 1). It would have been prima facie obvious to apply the method of separating nucleic acids as taught by Gossen and Weston with subsequent PCR and mutation detection as taught by Davis et al. in order to rapidly identify mutations in target DNA to use in applications such as for example, diagnostics, genotyping and prenatal testing.

5. Claims 57 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gossen et al. (USPN 5,602,300) and Weston et al. (USPN 5,246,851) as applied to claim 39 above, and further in view of Dower et al. (USPN 5,427,908).

The teachings of Gossen and Weston are described previously and fully meet the limitations of claim 39.

Gossen and Weston do not teach invitro packaging into bacteriophage particles.

Dower et al. teach invitro packaging into bacteriophage particles (see abstract).

One of ordinary at the time the invention was made would have been motivated to apply the method of separating nucleic acids as taught by Gossen and Weston with invitro packaging into bacteriophage as taught by Dower et al. in order to rapidly screen a DNA library of interest. Dower et al. state "Methods are needed which facilitate the screening process, thereby enabling DNA sequences which encode proteins of interest and particularly antibody molecules to be more readily identified, recloned and expressed (see col. 1 lines 36-40)." It would have been prima facie obvious to apply the method of separating nucleic acids as taught by Gossen and Weston with subsequent invitro packaging into bacteriophage as taught by Dower et al. in order to rapidly screen a DNA library of interest.

6. Claims 98 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gossen et al. (USPN 5,602,300) and Weston et al. (USPN 5,246,851) as applied to claims 39 and 97 above, and further in view of Sano et al. (USPN 5,665539).

The teachings of Gossen and Weston are described previously and fully meet the limitations of claim 39.

Gossen and Weston do not teach the proteins are linked via biotin to the nucleic acid and the protein is streptavidin.

Sano et al. teach linking DNA to a protein via a biotin/streptavidin interaction (see abstract).

One of ordinary at the time the invention was made would have been motivated to apply the method of separating nucleic acids as taught by Gossen and Weston with the biotin/streptavidin linkage as taught by Sano because Sano teach that streptavidin was found to bind rapidly and almost irreversibly to any molecule containing biotin with a high specific affinity (see col. 4 lines 63-65)." It would have been prima facie obvious to apply the method of separating nucleic acids as taught by Gossen and Weston with

the biotin/streptavidin linkage as taught by Sano et al. in order to link DNA to a protein in a strong and specific manner.

7. Claims 99 and 100 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gossen et al. (USPN 5,602,300), Weston et al. (USPN 5,246,851) and Seed (EP 0580305 A2) as applied to claims 39, 43, 44 and 80 above, and further in view of Sano et al. (USPN 5,665539).

The teachings of Gossen, Weston and Seed are described previously.

Gossen, Weston and Seed do not teach the proteins are linked via biotin to the nucleic acid and the protein is streptavidin.

Sano et al. teach linking DNA to a protein via a biotin/streptavidin interaction (see abstract).

One of ordinary at the time the invention was made would have been motivated to apply the method of separating nucleic acids as taught by Gossen, Weston and Seed with the biotin/streptavidin linkage as taught by Sano because Sano teach that streptavidin was found to bind rapidly and almost irreversibly to any molecule containing biotin with a high specific affinity (see col. 4 lines 63-65)." It would have been prima facie obvious to apply the method of separating nucleic acids as taught by Gossen Weston and Seed with the biotin/streptavidin linkage as taught by Sano et al. in order to link DNA to a protein in a strong and specific manner.

Response to Arguments

8. Applicants' arguments have been considered but are moot in view of the new ground(s) of rejection.

Summary

9. No claims were allowed.

Conclusion

10. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

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